

## **POINTS TO CONSIDER**

### **NON TECHNICAL ABSTRACT**

This study deals with the treatment of the Cytomegalovirus (CMV) infection occurring in patients following hemopoietic stem cell transplants. Viral infections are a major cause of illness and death post stem cell transplants.

In normal people, CMV infection causes no symptoms or a mild flu-like illness and usually gets better when the immune system controls the infection. The virus, however, remains hidden in the body for life. After a transplant, while the new immune system is growing back, the CMV can come out and cause life-threatening disease. Patients can develop fevers and damage to organs such as the lungs, gut, and eyes. Although there are drugs available currently in use for the prevention and treatment of CMV infection, these drugs have significant side effects most commonly affecting the bone marrow and the kidneys, and may also fail to work.

We want to see if we can prevent CMV infection from happening by giving the patient a kind of white blood cell called T-cells, which have been trained to attack CMV infected cells. We will grow these T-cells from blood taken from the donor at the time of bone marrow harvest, and then we will test them to make sure they can kill the virus infected cells.

The main purpose of this study is to see if these T-cells are safe. To make these CMV specific T cells, we will obtain blood from the stem cell donor and grow a special type of cell called dendritic cells which will stimulate the T cells. We will then transfer an adenovirus vector that carries the CMV gene into the dendritic cells. These dendritic cells will then be treated with radiation so they cannot grow and used to stimulate T cells. This stimulation will train the T cells to kill cells infected with CMV. We will then grow these CMV specific CTLs by more stimulation with CMV infected B cells (lymphoblastoid cells) from the donor, because these cells are more easily grown than the dendritic cells.